



Food and Drug Administration
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September 24, 2014

REACH Health, Incorporated
Ms. Beth DeStasio
Director, Regulatory Affairs & Strategy
10745 Westside Way
Alpharetta, GA 30009

Re: K142123
Trade/Device Name: REACH Access Telemedicine Dose Calculator
Regulation Number: 21 CFR 868.1890
Regulation Name: Drug Dose Calculator
Regulatory Class: II
Product Code: NDC, LLZ, OUG
Dated: August 4, 2014
Received: August 5, 2014

Dear Ms. DeStasio:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K142123

Device Name

REACH Access Telemedicine Dose Calculator

Indications for Use (Describe)

The REACH Access Telemedicine Dose Calculator is designed for used by trained clinicians to calculate any individual patient's dose for a given agent based on a weight determined by the clinician. Drug dosing for a patient must be made only after careful consideration of the full clinical status of the patient by the ordering clinician and the software provides no validation as to the appropriateness of the entered weight-based dose. The REACH Access Telemedicine Dose Calculator is a convenience feature for trained clinicians based upon accurately entered data. No medical decision should be based solely upon the results provided by this software program. The REACH Access Telemedicine Dose Calculator is intended to be used as an aid in the consultative process and does not overrule or replace physician judgment or diagnosis.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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5. 510(k) Summary

Submitter: REACH Health, Inc.
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Contact person: Beth DeStasio
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Fax number: (678) 710-9064

Date prepared: 8/1/2014

Trade name: REACH Access Telemedicine Dose Calculator
Common name: Drug Dose Calculator
Primary Product Code: NDC
Classification Number: 21 CFR 868.1890
Class: II
Secondary Product Codes: LLZ (Picture archiving and communications system), OUG (Medical Device Data System)

510(k) Number: K142123

Substantial equivalence claimed to: PICIS WEIGHT BASED DOSE CONVERTER, K121542

Description:

REACH Access is a highly integrated Telemedicine solution that combines workflow, video conferencing, electronic clinical documentation, and medical imaging into a comprehensive and secure internet-based service. It enables healthcare organizations to form virtual collaborative care teams which are created based on patient need rather than availability of specialists. With a flexible, template-based design tool, REACH Access can build template sets which support clinician workflow and documentation relevant to numerous protocols.

REACH Access templates support a specific point-in-time consult. This means the workflow processes and clinical content is captured and coordinated with the integrated audio/video conference to allow a remote provider to collaborate with caregivers at a different location in the care of a patient.

The normal process is the patient is assessed and treated in the Emergency Department (ED) by ED staff and the video conference support of a specialist consultant. After reviewing key patient data and assessing the patient, the remote consultant renders an impression, recommends the treatment order as indicated, and helps determine the appropriate disposition. This usually concludes the consultant's part in the session. The ED continues to render care by completing the recommended treatment order and monitoring patient vital signs and other assessments. The disposition commonly consists of transferring the patient from the originating hospital to the Hub with which the consultant is associated. However, if there is adequate local support, the decision may be made to admit the patient to the local facility.

This process/workflow is similar to what may be required for other point-in-time consults needed to provide additional remote assistance to caregivers for other patient problems or conditions at the patient point of care. A protocol/template can be part of a coordinated collection of toolsets. The flexible template design process in REACH Access addresses the need for multiple protocols to support the various phases of care. The flexibility of the tool allows for the unique presentation of data for a specific condition; e.g., stroke, in the format most relevant to the patient's current need/condition. This flexibility can be replicated to address similar capability. This can be handled through a combination of both individual and a series of protocols arranged in clinically logical groups.

Indications for Use:

The REACH Access Telemedicine Dose Calculator is designed for use by trained clinicians to calculate any individual patient's dose for a given agent based on a weight determined by the clinician. Drug dosing for a patient must be made only after careful consideration of the full clinical status of the patient by the ordering clinician and the software provides no validation as to the appropriateness of the entered weight-based dose. The REACH Access Telemedicine Dose Calculator is a convenience feature for trained clinicians based upon accurately entered data. No medical decision should be based solely upon the results provided by this software program. The REACH Access Telemedicine Dose Calculator is intended to be used as an aid in the consultative process and does not overrule or replace physician judgment or diagnosis.

Substantial Equivalence:

The REACH Access Telemedicine Dose Calculator is substantially equivalent to the predicate Device, the Picis Weight Based Dose Converter.

	REACH Access	Picis (K121542)
Manufacturer	REACH Health, Inc.	Picis Incorporated
510(k)	NA	K121542
Indication for use	The REACH Access Telemedicine Dose Calculator is designed for used by trained clinicians to calculate any individual patient's dose for a given agent based on a weight determined by the clinician. Drug dosing for a patient must be made only after careful consideration of the full clinical status of the patient by the ordering clinician and the software provides no validation as to the appropriateness of the entered weight-based dose. The REACH Access Telemedicine Dose Calculator is a convenience feature for trained clinicians based upon accurately entered data. No medical decision should be based solely upon the results provided by this software program. The REACH Access Telemedicine Dose Calculator is intended to be used as an aid in the consultative process and does not overrule or replace physician judgment or diagnosis.	The Picis Weight Based Dose Converter is designed for use by trained clinicians to calculate any individual patients dose for a given agent based on a weight based dose determined by the clinician. Drug dosing for a patient must be made only after careful consideration of the full clinical status of the patient by the ordering clinician and the software provides no validation as to the appropriateness of the entered weight based dose. The Picis Weight Based Dose Converter is not a substitute for clinical reasoning. The Picis Weight Based Dose Converter is a convenience feature for trained clinicians based upon accurately entered data. No medical decision should be based solely upon the results provided by this software program.
Target Population	In-hospital patients	In-hospital patients
User Population	Trained healthcare professionals	Trained healthcare professionals
Dose Computation	Software based application used to compute total drug dose	Software based application used to compute total drug dose
Algorithms	Uses simple mathematical equation to calculate dosing based on patient weight	Uses simple mathematical equation to calculate dosing based on patient weight and numerical dose and units
Testing	Validation and Verification	Validation and Verification

Substantial Equivalence Discussion

The REACH Access Telemedicine Dose Calculator is substantially equivalent to the predicate Device, the Picis Weight Based Dose Converter. The REACH Access Telemedicine Dose Calculator has the same intended uses, technological characteristics and principles of operation as the predicate device. The minor technological differences between the REACH Access Telemedicine Dose Calculator and the predicate device raise no issues of safety or effectiveness. Both devices calculate an individual patient's dose for a given agent based on a weight based dose determined by the clinician.

Conclusion:

The performance of the REACH Access Telemedicine Dose Calculator is substantially equivalent to that of the Picis Weight Based Dose Converter and raises no safety or effectiveness issues and performs as well or better than the predicate device.